# Effects of a structured progressive taskoriented circuit training program to enhance walking competency after stroke

Published: 03-06-2008 Last updated: 10-05-2024

The primary aim of this study is to evaluate the effects of a structured, progressive taskoriented fitness training program applied in a group of 8 to 10 patients on perceived outcome of mobility after stroke when compared to individually-tailored...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Interventional

# Summary

### ID

NL-OMON31492

**Source** ToetsingOnline

Brief title FIT-STROKE trial

### Condition

- Neurological disorders NEC
- Vascular haemorrhagic disorders

#### Synonym

cerebro vasculair accident, stroke

**Research involving** 

Human

### **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** ZonMW

### Intervention

Keyword: cerebrovascular disorders, costs, exercise, health related quality of life

### **Outcome measures**

#### **Primary outcome**

Primary outcome will be the Stroke Impact Scale (mobility part) and cost

effectiveness (EuroQoL).

#### Secondary outcome

endurance, gait speed, muscle strength of lower limbs, chair rising and stair

climbing tests, confidence not to fall, instrumental ADL, fatigue, anxiety and

depression, and health perception in general.

# **Study description**

#### **Background summary**

The number of stroke patients in the Netherlands is 7.5 per 1000 inhabitants and keeps increasing (Struijs 2005). With that costs increase too, and these costs are suspected to be over one billion Euros (Evers 2004). Previous studies show that walking ability is often diminished in these patients and with that mobility too (vd Port, Lord, Kwakkel). A qualitative study showed that loss of independence in mobility is one of the most invalidating factors for patients with stroke. (Pound). In addition will inactivity lead to secondary complications like loss of endurance, muscle atrophy, osteoporoses and circulation problems of the lower extremities. (Gordon) and with that quality of life in general. A meta-analysis showed that task-oriented circuit training in groups is effective in improving walking competency after stroke (van de Port). However, the effects of interventions in chronic stroke patients and the cost effectiveness of these programs compared have hardly been investigated.

#### **Study objective**

The primary aim of this study is to evaluate the effects of a structured, progressive task-oriented fitness training program applied in a group of 8 to 10 patients on perceived outcome of mobility after stroke when compared to individually-tailored physiotherapy in the community. The second aim is to examine the cost-effectiveness.

#### Study design

A multicentre single blinded randomised clinical trial.

#### Intervention

Group training containing 8 to 10 workstations focused on improving balance, walking ability, walking related activities like transfers, climbing stairs and endurance. The program will be tailor-made considering the ability of the patient. Important is that the program can be progressive by adding weight, or increasing the number of repetitions. The program will last 12 weeks with two sessions of 90 minutes per week. During this period the patient holds a dairy about activities and special remarks that might influence the results.

#### Study burden and risks

The intervention given in this research project is believed to be comparable to the regular physical therapy intervention when considered burden for the patient. The patients will have to fill out some questionnaires which will not give much burden. Also some physical test are included of which the main part includes tests that are part of regular physical therapy (6 minute walking test, 10 meter walking test, motricity index). We therefore have the opinion that the extent of burden is not too heavy for these patients. Risks associated with participation in this study are minor.

# Contacts

Public Universitair Medisch Centrum Utrecht

Heidelberglaan 100 3508 GA Utrecht NL **Scientific** Universitair Medisch Centrum Utrecht Heidelberglaan 100 3508 GA Utrecht NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

Patients after stroke during inpatient rehabilitation age over 18 years being able to walk at least 10 m independently (Functional Ambulation Categories >=4) Being motivated to follow 24 session of physical therapy expressed by signing informed consent

### **Exclusion criteria**

Cognitive problems (Mini Mental State Examination <24 punten) Subarachnoidale haemorrhage Communication problems (Utrecht Communicatie Onderzoek < 4 punten) Patients living more than 30 km from the rehabilitation centre

# Study design

### Design

Study type: Intervention model: Interventional

Parallel

4 - Effects of a structured progressive task-oriented circuit training program to en ... 13-05-2025

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2008
Enrollment:	250
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	03-06-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	21-05-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	13-05-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

# **Study registrations**

# Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register

ССМО

ID NL20850.041.07